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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/849,498	05/19/2004	Yi-Yan Yang	S1507.70000US00	6009
23628 7590 01/19/2007 WOLF GREENFIELD & SACKS, PC FEDERAL RESERVE PLAZA 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			EXAMINER HIBBERT, CATHERINE S	
			ART UNIT	PAPER NUMBER
			1609	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		01/19/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/849,498	<b>Applicant(s)</b> YANG ET AL.	
	<b>Examiner</b> Catherine S. Hibbert	<b>Art Unit</b> 1609	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-16 and 44 and 48, drawn to an article and a composition (claims 1-16) comprising a nanoparticle having a first portion capable of associating a nucleic acid and a second portion capable of associating a drug, and to a kit and a composition (claims 44 and 48) comprising a nanoparticle, a drug and a nucleic acid, classified in class 424, subclass 489.
  - II. Claims 17-23, drawn to a composition comprising a chemical having the structure  $-(X-Y-Z)_q-(X'-Y'-Z')_p-$  classified in class 520, subclass 1.  
Group II further contains claims directed to patentably distinct species.
  - III. Claim 24, drawn to a method of delivering a non-nucleic acid drug to a subject, comprising associating the non-nucleic acid drug with the polymer of claim 18 and administering the complex to a subject, classified in class 424, subclass 489.  
Group III further contains claims directed to patentably distinct species.

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- IV. Claim 25, drawn to a method of delivering a nucleic acid to a subject, comprising associating the nucleic acid with the polymer of claim 18 and administering the complex to a subject, classified in class 514, subclass 44.

Group IV further contains claims directed to patentably distinct species.

- V. Claims 26-39, drawn to a method of administering a drug and a nucleic acid to a subject, comprising a drug/nucleic acid complex, classified in class 514, subclass 44.

- VI. Claims 40-43, drawn to a method of making a drug delivery composition, classified in class 514, subclass 44.

- VII. Claims 45-47, drawn to a kit comprising an amphoteric polymer, classified in class 520, subclass 1.

Note, if applicant chooses Groups II, III, or IV, an election of species will be further required.

- 2. The inventions are distinct, each from the other because of the following reasons:  
Inventions II and I are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the

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intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as a composition for making macroparticles such as chromatography resins or immunodiagnostic reagent supports and the inventions are deemed patentably distinct because there is nothing on this record to show them to be obvious variants.

Invention I is unrelated to III-VII because the methods of III-VI do not require the nanostructure of Group I, and the kit of Group VII does not require the nanostructure of Group I.

Inventions II and III-IV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product of Group II can be used in two materially different, mutually exclusive methods, specifically delivery of a nucleic acid (Group IV) or delivery of a non-nucleic acid drug (Group III).

Group II is not related to V, VI or VII because V, VI or VII do not require the polymer of Group II.

Groups III & IV are unrelated because they are mutually exclusive processes.

Groups III & IV are unrelated to V, VI or VII because V, VI or VII do not involve the polymer required in Groups III & IV.

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Group V is unrelated to VI because the process of VI prevents formation of the drug/nucleic acid complex required in Group V.

Group V is unrelated to VII because the process of V does not require the polymer of Group VII.

Groups VI & VII are related as product & method of use, the method of Group VI can be practiced with a materially different product such as a polymer which is not amphoteric. Also the kit as claimed can be used in a materially different process such as a process of making a chromatography resin.

3. Groups II, III and IV contain claims directed to the following patentably distinct species described in claim 17:

the chemical structure  $-(X-Y-Z)_q-(X'-Y'-Z')_p-$  wherein X, Y, and Z, are selected independently from a subset of structures and at least one of X', Y' and Z' are selected independently from a subset of structures, and wherein, R is H, an alkyl or a substituted alkyl, R' is a hydrophobic group; and n, m, p, n', m' and p' are greater than zero.

The applicant is required to elect a single species whereby X, Y, Z, X', Y', Z', R, R', n, m, p, n', m' and p' are specified. The species are independent or distinct because each species is an individual chemical structure which requires an independent search of the prior art. Because the claims 18-25 depend from claim 17, the requirement of

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applicant for election of species from claim 17 also applies to claims 18-23 (Group II) and claims 24 and 25 (Groups III and IV).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 17-25 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. A telephone call was made to Timothy J. Oyer, Ph.D. on (617) 646-8000 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

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requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Notice of Possible Rejoinder***

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise

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require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Election/Restrictions***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Hibbert whose telephone number is 571-

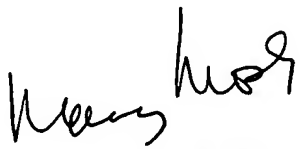
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272-0235. The examiner can normally be reached on Monday-Friday, 7:30 AM-5:00 PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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**MARY E. MOSHER, PH.D.**  
**PRIMARY EXAMINER**  
1/4/07